SOP# HRP 01.16
Initial Approval Date: 1/8/09

RESEARCH PARTICIPANT OUTREACH PROGRAM

OBJECTIVE:

To establish a documented process for research participants to express their questions and concerns.

SCOPE & POLICY:

On November 17, 2008 the VHA issued Directive 2000-079, "Research Participant Outreach Program". The Directive set out a policy establishing Research Participant Outreach Programs at VHA facilities performing human research.

The VAMHCS Research Service concurs with the VHA's stated view that participants' questions and concerns help identify ways to enhance safeguards, thereby better protecting their rights and welfare. Research Participant Outreach Programs not only help improve relationships with, and safety of, research participants, they can help improve public trust in VA research programs. Prior to this VHA Directive, the Research Service has conducted and reported on a research participant satisfaction survey project, periodically displayed a poster with informational brochures in a public area of the VAMHCS, conducted outreach on VA Research Days, included the VAMHCS research Compliance Office on VAMHCS informed consent forms, and, through the Research Service internet site, publicized the Research Compliance Office as a contact for complaints and suggestions. A participant outreach program has been included in the VAMHCS Human Research Protection Program since 2003.

It is the policy of the VAMHCS Research Service to seek feedback from current, prospective or past research participants or their designated representatives by establishing and promoting a Research Participant Outreach Program (RPOP).

RESPONSIBILITIES:

The VAMHCS Research & Development Service and the VAMHCS Research Compliance Officer are responsible for the implementation of this policy.

The Research Compliance Officer (RCO) is responsible for:

- Scheduling poster displays, electronic messages and other potential avenues of community outreach through the VAMHCS Office of Public Relations.
- Conducting public education and survey activities at VA Research Day and/or other opportunities for public outreach;
- Maintenance of the Research Service website, ensuring that Contact information is accurate;
- Intake of the comments, complaints and suggestions;
- Conducting or supervising the follow-up on the comments, complaints and suggestions;
- Conducting satisfaction surveys to assess the experiences of VAMHCS research participants.

The Principal Investigator is responsible for:

- Ensuring that research participants can express concerns, complaints or suggestions without fear of threat, restraint, discrimination or reprisal;
- Distributing the VHA brochure, "Volunteering in Research – Here are some things you need to know" to potential research participants in settings where they may recruit participants (e.g., clinic waiting areas), and to each prospective participant, and surrogate where necessary, when an individual is approached to take part in a project;
- Educating potential participants that the IRB and the Office of Research Compliance are independent of the research and are available for expressing questions or concerns;
- Informing study participants and their families/advocates during the informed consent process that complaints can be lodged with the RCO and the IRB;
- Ensuring that the RCO has accurate information if/when a comment/complaint has been lodged.

SEE ALSO

VAMHCS Research Service SOP	HRP 01.02: Human Research Protection Program
VAMHCS Research Service SOP	HRP 01.07: Addressing and Responding to Comments, Complaints and Suggestions Related to the Human Research Protection Program

PROCEDURES:

1. The VAMHCS Office of Research Compliance conducts participant outreach activities.
   1.1. Respond to and process participants' or others' complaints, comments and

suggestions. This is done according to HRP 01.07 (Addressing and Responding to Comments, Complaints and Suggestions Related to the Human Research Protection Program)

1.1.1. Access BRAAN/CICERO for information regarding the study when necessary

1.1.2. Contact the investigator to obtain and verify current information about the study when participant questions arise.

1.2. Distribute the VHA brochures, "Volunteering in Research – Here are some things you need to know" to investigators.

1.2.1. Brochures need to be labeled with contact information for the RCO.

1.3. Maintain current information on the Research Service website (www.maryland.research.va.gov), in particular:

1.3.1. the "Contact Us" page (contains instructions to the community for expressing complaints, comments and suggestions) and

1.3.2. the "For Investigators" page (instructions to investigators and an active link to the COACH website for information on ordering brochures).

1.3.3. Periodically display the COACH informational poster in public areas throughout the VAMHCS.

1.4. Perform educational outreach activities at the annual VA Research Day.

1.5. Ensure that the IRB's ICF templates include the contact information for the ORC and requests permission for the ORC to contact the participant.

2. Investigators educate current and potential participants in the following ways:

2.1. distribute the VHA brochure, "Volunteering in Research – Here are some things you need to know" during their recruitment and enrollment activities. to potential research participants in settings where they may recruit participants (e.g., clinic waiting areas), and to each prospective participant, and surrogate where necessary, when an individual is approached to take part in a project.
   2.1.1. This requirement applies when written documentation of informed consent is waived, but not when informed consent has been waived. NOTE: The Institutional Review Board (IRB) may waive informed consent altogether or it may just waive written documentation of the informed consent but still require that informed consent be obtained from the subject or surrogate
   2.1.2. Obtain the brochures through the Office of Research Compliance. Larger Centers should make arrangements with the ORC to order brochures directly from COACH and to properly label the brochures with ORC contact information.
   2.1.3. Establish procedures to make the brochures available to current and potential participants through their clinics and other recruitment activities.
   2.1.4. Establish procedures to document outreach activities (for example, how many brochures distributed, reasons why individuals decline the brochure, etc.). This will be assessed at the time of the triannual audits.
2.2. At the time of enrollment and during the consent process, inform the participant that the IRB and the Office of Research Compliance are independent of the research and are available for expressing questions or concerns.

3. The VAMHCS Office of Research Compliance evaluates the outreach program by:
   3.1. following up on participants' complaints, comments and suggestions according to HRP 01.07;
   3.2. conducting a satisfaction survey of potential, current and past research participants at least annually,
   3.3. distributing satisfaction surveys through investigators or directly to research participants (f permission for contact is obtained),
   3.4. during the triannual audits, assessing the investigator's outreach program (see 2.1.3 above).

REFERENCES:

VHA Directive 2008-079	Research Participants Outreach Program

APPROVAL

This SOP entitled "Research Participants Outreach Program" has been approved by the Medical Center Director, effective 1/8/09.